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ZEVEX
INCORPORATED

510(K) SUMMARY FOR K012147

10/03/2001

Submitter
ZEVEX, Inc.
4314 ZEVEX Park Lane
Salt Lake City, UT 84123
(801) 264-1001
Contact: Susan Schmidt

Trade Name: ZEVEX, Inc, Enteral Feeding Sets for Gravity and Pump Use
Common Name: Enteral Feeding Sets for Gravity and Pump Use
Classification Name: Tubes, Gastrointestinal (and Accessories)

Predicates: K954735 Infusion pump, enteral, external
(disposable sets were included as accessories)
K862489 Enteral Feeding Sets for Gravity and Pump Use

The devices in this product family are used to dispense liquid nutrients (feeding solution) at a user controlled rate. These enteral feeding sets interface with the patient's feeding tube and may use gravity or an enteral feeding pump to dispense feeding solution. The devices may include a bag to contain the feeding solution and/or a spike to connect to a pre-filled container.

Summary of Device Comparision:
New Device Models:

Spike Pump Set	S0010
Spike Pump Set with Anti Free Flow Fitting	2L8018-AF
500 ml Bag Pump Set	S0500
500 ml Bag Pump Set with Anti Free Flow Fitting	2L0500-AF
1200 ml Bag Pump Set	S1200
1200 ml Bag Pump Set with Anti Free Flow Fitting	2L8020-AF
1200 ml Bag Gravity Set	2L8001
300 ml Intermittent Feeding Gravity Set	2L8050

510(K) SUMMARY FOR K012147 (continued)

ZEVEX INCORPORATED

Model	Comparison Criteria	Modified Device	Predicate Device
All	Enteral Adapter	'Slip Loc' design New Base Material, USP Class VI	Original design Original Base Material, USP Class VI
All	Cap, Enteral Adapter	Designed to fit 'slip loc' enteral adapter Same Base Material	Designed to fit original enteral adapter Same Base Material
All anti free flow models	Pump Fitting	Anti Free Flow Fitting New Base Material, USP Class VI	Pinch Clip Occluder anti free flow device Original Base Material, USP Class VI
500 ml Bags, 300 ml intermittent gravity set	Bag Assembly	Smaller surface area Same material	1200 ml (larger surface area) Same material
All	All other components	Same	Same
All	Intended Use	Same	Same
All	Biocompatibility of final product	Only material changes are 'slip loc' enteral adapter and anti free flow fitting. Both new materials are USP Class VI and colorants are approved by FDA for food grade applications.	Original materials were USP class VI.
All	Sterilization	Not sterile	K954735 disposable sets are not sterile
All	Labeling	Added additional pump and gravity set use information Added anti free flow information (where applicable)	Referenced pump procedures

The anti free flow device, in the new models, consists of a tubing fitting which has been modified to include an anti free flow feature, which automatically prevents flow when the set is removed from the pump. Testing included a volumetric accuracy test, a test to check the blow by pressure of the anti free flow fitting, a bond test to check the bond strength between components, and a cytotoxicity test to check the biocompatibility of the new materials. The test results indicated that the modifications have not reduced the safety or effectiveness of the product or created new issues regarding safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 2 2001

Ms. Susan P. Schmidt
Regulatory Affairs Manager
ZEVEX®, Inc.
4314 ZEVEX Park Lane
SALT LAKE CITY UT 84123

Re: K012147
Trade/Device Name: ZEVEX® Enteral Feeding Sets for Gravity and Pump Use
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: 78 KNT
Dated: October 3, 2001
Received: October 4, 2001

Dear Ms. Schmidt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K012147

NOV 0 2 2001

510(k) Number (if known): K012147

Device Name: Enteral Feeding Sets for Gravity and Pump Use

Indications For Use:

The devices in this product family are used to dispense liquid nutrients (feeding solution) at a user controlled rate. These enteral feeding sets interface with the patient's feeding tube and may use gravity or an enteral feeding pump to dispense feeding solution. The devices may include a bag to contain the feeding solution and/or a spike to connect to a pre-filled container.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012147

(Optional Format 3-10-98)

Prescription Use ✓